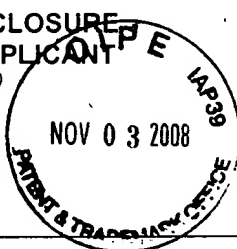


Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

Application Number	09/754,775
Filing Date	January 4, 2001
First Named Inventor	Grainger, David
Group Art Unit	1617
Examiner Name	Kim, Jennifer

Sheet 1 of 4

Attorney Docket No: 295.009US3

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-4,826,876	05/02/1989	Ellis, D. , et al.	12/21/1987
	US-7,094,550	08/22/2006	Grainger, David J., et al.	03/26/2002

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T ²
	EP-0290012A1	11/09/1988	Marquardt, H. , et al.	
	JP-04-501848 (w/ English Abstract)	04/02/1992	Hanson, S. , et al.	
	WO-89/05148A1	06/15/1989	Harker, L. A., et al.	
	WO-92/00330A1	01/09/1992	Iwata, K. K., et al.	
	WO-92/08480A1	05/29/1992	Owaga, Y. , et al.	
	WO-94/05265A1	03/17/1994	Berde, C. B., et al.	
	WO-94/26303A1	11/24/1994	Grainger, D. J., et al.	
	WO-96/40098A2	12/19/1996	Grainger, D. J., et al.	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"1992 Keystone Symposia on Molecular and Cellular Biology. Inflammation, growth regulatory molecules and atherosclerosis. January 13-19, 1992. Abstracts", J Cell Biochem Suppl., 50(S16A), Abstracts E111,(1992), 1-30	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Non Final Office Action mailed 02-01-1999", 6 pgs	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Non Final Office Action mailed 09-29-1999", 5 pgs	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Notice of Allowance mailed 09-25-2000", 2 pgs	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Preliminary Amendment filed 12-05-1997", 2 pgs	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Response filed 03-21-2000 to Non Final Office Action mailed 09-29-1999", 4 pgs.	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Response filed 07-30-1999 to Non Final Office Action mailed 02-01-1999", 4 pgs	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Response filed 09-08-2000 to Final Office Action mailed 06-08-2000", 3 pgs	
		"Application Serial No. 08/973,570 (Atty. Ref. 295.009US2), Final Office Action mailed 06-08-2000", 4 pgs.	

EXAMINER**DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	09/754,775
Filing Date	January 4, 2001
First Named Inventor	Grainger, David
Group Art Unit	1617
Examiner Name	Kim, Jennifer

Sheet 2 of 4

Attorney Docket No: 295.009US3

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"Application Serial No. 10/729,056 (Atty Ref. No. 295.009US4), Amendment and Response filed 10-01-2007 to Non-Final Office Action dated 07-03-2007", 11 pgs.	
		"Application Serial No. 10/729,056 (Atty Ref 295.009US4), Non-Final Office Action mailed 09-03-2008", 16 pgs.	
		"Application Serial No. 10/729,056 (Atty. Ref. 295.009US4), Final Office Action mailed 12-11-2007", 20 pgs.	
		"Application Serial No. 10/729,056 (Atty. Ref. 295.009US4), Non Final Office Action mailed 07-03-2007", 17 pgs.	
		"Application Serial No. 10/729,056 (Atty. Ref. No. 295.009US4), Amendment and Response filed 3-11-2008 to Final Office Action mailed 12-11-2007", 11 pgs.	
		"Application Serial No. 11/231,256 (Atty Ref 295.011US3), Notice of Allowance mailed 07-29-2008", 4 pgs.	
		"Application Serial No. 11/231,256 (Atty Ref 295.011US3), Response filed 5-29-2008 to Final Office Action mailed 2-29-2008", 4 pgs.	
		"Application Serial No. 11/231,256 (Atty Ref. 295.011US2), Amendment and Response filed 12-06-2007 to Office Action mailed 09-26-2007", 5 pgs	
		"Application Serial No. 11/231,256 (Atty. Ref. 295.011US3), Final Office Action mailed 02-29-2008.", 8 pgs.	
		"Application Serial No. 11/231256 (Atty. Ref. 295.011US3), Non Final Office Action Mailed 09-26-2007", 7 pgs	
		"Application Serial No. 96921577.1 (Atty Ref 295.009EP1), Communication mailed 4-6-2006", 3 pgs.	
		"Application Serial No. 96921577.1 (Atty Ref 295.009EP1), Communication mailed 6-16-2003", 13 pgs.	
		"Application Serial No. 96921577.1 (Atty Ref 295.009EP1), Response filed 12-12-2006", 21 pgs.	
		"European Application Serial No 07021554.6 (Atty Ref 295.009EP2), Extended European Search Report mailed 09-09-2008", 8 pgs.	
		"International Application Serial No. PCT/US96/10211 (Atty Ref 295.009WO1), International Search Report mailed 5-20-1997", 5 pgs.	
		"International Application Serial No. PCT/US96/10211 (Atty Ref 295.009WO1), Written Opinion mailed 6-20-1997", 8 pgs.	
		"Japanese Application No. 9-502239 (Atty Ref 295.009JP1), Notice of Reasons for Rejection mailed 10-30-2007", (w/ English Translation), 19 pgs.	
		"Japanese Application No. 9-502239 (Atty Ref 295.009JP1), Response filed 4-30-2008 to Notice of Reason for Rejection mailed 10-30-2007", (w/ English Translation), 78 pgs.	
		BJÖRKERUD, S., et al., "Effects of Transforming Growth Factor-β1 on Human Aterial Smooth Muscle Cells In Vitro", <u>Arteriosclerosis and Thrombosis</u> ; 11, (2007),(1991), 892-902	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	09/754,775
Filing Date	January 4, 2001
First Named Inventor	Grainger, David
Group Art Unit	1617
Examiner Name	Kim, Jennifer

Sheet 3 of 4

Attorney Docket No: 295.009US3

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		DRESEL, P E., et al., "Cytochalasin-B and phloretin depress contraction and relaxation of aortic smooth muscle", <u>Eur J Pharmacol</u> , 144(2), (1987), 153-157	
		GRAINGER, D. J., "Control of the Proliferation and Differentiation of Vascular Smooth Muscle Cells", <u>PhD Thesis</u> , University of Cambridge, (September, 1992), 192 pgs.	
		GRAINGER, D. J., et al., "Tamoxifen: Teaching an Old Drug new Tricks?", <u>Nature Medicine</u> , 2(4), (April, 1996), 381-385	
		KANGAS, L., "Introduction to toremifene", <u>Breast Cancer Res Treat</u> , (1990-Aug-16), S 3-7	
		KHANNA, A. K., "Mechanism of the combination immunosuppressive effects of rapamycin with either cyclosporine or tacrolimus.", <u>Transplantation</u> , 70(4), (Aug. 27, 2000), 690-694	
		KHANNA, A., "TGF-BETA Provides the Rationale for the Synergistic Immunsuppression with rapamycin (RaPA), Cyclosporine (CsA) and Tacrolimus (TAC).", <u>Transplantation</u> , 67(7), (Abstract Only) (April 15, 1999), 2 pgs.	
		MCKENNEY, P. A., et al., "Cyclosporine A Does Not Inhibit Restenosis in Experimental Angioplasty", <u>Circulation</u> , 84(4), (1991), (Abstract 0278), 1 pg.	
		NUOVO, M. A., et al., "Endometrial Polyps in Postmenopausal Patients receiving Tamoxifen", <u>Int J Of Gynecological Pathology</u> ; Raven Press Ltd., NY, (1989), 125-131	
		OWENS, G. K., et al., "Transforming Growth Factor β -induced growth inhibition and cellular hypertrophy in cultured vascular smooth muscle cells", <u>J. Cell. Biol.</u> 107 (2), (August, 1988), 771-780	
		POTTER, G. A., et al., "A mechanistic hypothesis for DNA adduct formation by tamoxifen following hepatic oxidative metabolism", <u>Carcinogenesis</u> , 15 (3), (1994), 439-442	
		SAWADA, T., et al., "Fifty two-week Oral Toxicity Study of Toremifene Citrate (NK622)", <u>Pharmacometrics</u> , (w/ English Translation), (May 11, 1992), 357-373 (33 pgs)	
		STOCKWELL, B. R., et al., "TGF- β -signaling with small molecule FKBP12 antagonists that bind myristoylated FKBP12-TGF- β type I receptor fusion proteins.", <u>Chem Biol</u> , 5(7), (July, 1998), 385-95	
		STRAUSS, B H., et al., "Angiographic Predictors of Restenosis in the Coronary Wallstent.", <u>Circulation</u> , 82(4), (Abstract No. 2142), (1990), 1 pg.	
		SWINFORD, R. D., et al., "Rapamycin (RAPA) enhances transforming growth factor beta (TGF- β 1) Expression in Immortalized Rat Proximal Tubules Cells (IRPTC)", <u>American Society of Transplant Physicians (ASTP 1998 Abstracts)</u> , (Abstract No. 396), (1998), 1 pg.	
		WARRI, A. M., et al., "Apoptosis in toremifene-induced growth inhibition of human breast cancer cells in vivo and in vitro", <u>J Natl Cancer Inst.</u> , 85(17), (1993), 1412-1418	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1448)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	09/754,775
Filing Date	January 4, 2001
First Named Inventor	Grainger, David
Group Art Unit	1617
Examiner Name	Kim, Jennifer

Sheet 4 of 4

Attorney Docket No: 295.009US3

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		WASOWSKA, B. A., et al., "Adjunctive rapamycin and CsA treatment inhibits monocyte/macrophage associated cytokines/chemokines in sensitized cardiac graft recipients", <u>Transplantation</u> , 71(8), (2001), 1179-1183	
		YOUNG, H., et al., "Pharmacokinetics and Biodistribution of Radiolabelled Idoxifene: Prospects for the Use of PET in the Evaluation of a Novel Antioestrogen for Cancer Therapy", <u>Nucl. Med. Bio.</u> 2(4), (1995), 405-411	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached